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and Salix Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED; AUROBINDO PHARMA USA INC.; and AURO PEPTIDES LTD., Defendants.	Civil Action No. 23-00170 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Plaintiffs") by way of Complaint against Defendants Aurobindo Pharma Limited, Aurobindo Pharma USA Inc., and Auro Peptides Ltd. (collectively, "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principal place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 208745, which covers Trulance®.

3. Upon information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India, having a place of business and Corporate Office at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad 500 032, Telangana, India. Upon information and belief, Aurobindo Pharma Limited has a Registered Office at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad 500 038, Telangana, India. Upon information and belief, Defendant Aurobindo Pharma Limited is an agent and/or affiliate of Defendants Aurobindo Pharma USA Inc. and Auro Peptides Ltd.

4. Upon information and belief, Defendant Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Defendant Aurobindo Pharma USA Inc. is an agent and/or affiliate of Aurobindo Pharma Limited and Auro Peptides Ltd.

5. Upon information and belief, Defendant Auro Peptides Ltd. is a corporation organized and existing under the laws of the Republic of India, having a place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad 500 032, Telangana, India. Upon information and belief, Auro Peptides Ltd. has a Principal Brach Location at 4th Floor, Sy. No. 71 & 72, Indrakaran Village, Sangareddy Mandal, Medak District 502 309, Telangana, India. Upon information and

belief, Defendant Auro Peptides Ltd. is an agent and/or affiliate of Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 7,041,786 ("the '786 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231 patent"), 10,011,637 ("the '637 patent"), 11,142,549 ("the '549 patent"), and 11,319,346 ("the '346 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market their generic plecanatide oral tablets, 3 mg ("Defendants' generic plecanatide oral tablets").

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Upon information and belief, this court has jurisdiction over Defendant Aurobindo Pharma Limited. Upon information and belief, Aurobindo Pharma Limited is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Aurobindo Pharma Limited directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, Aurobindo Pharma Limited purposefully has conducted and continues to conduct business in this judicial district.

Upon information and belief, Aurobindo Pharma Limited has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Upon information and belief, this court has jurisdiction over Aurobindo Pharma USA Inc. Upon information and belief, Aurobindo Pharma USA Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Aurobindo Pharma USA Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Aurobindo Pharma USA Inc.'s generic plecanatide oral tablets. Upon information and belief, Aurobindo Pharma USA Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Aurobindo Pharma USA Inc. has its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Aurobindo Pharma USA Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Upon information and belief, this court has jurisdiction over Defendant Auro Peptides Limited. Upon information and belief, Auro Peptides Limited is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Auro Peptides Limited directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, Auro Peptides Limited purposefully

has conducted and continues to conduct business in this judicial district. Upon information and belief, Auro Peptides Limited is the holder of FDA Drug Master File No. 36321 for plecanatide.

11. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of their generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Defendants' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of their proposed generic drugs. Upon information and belief, Defendants intend to direct sales of their drugs into New Jersey, among other places, once they have the requested FDA approval to market them. Upon information and belief, Defendants will engage in marketing of Defendants' generic plecanatide oral tablets in New Jersey upon approval of their ANDA.

12. Upon information and belief, including, based on, *inter alia*, Defendants' website and Defendants' publicly-available press releases, Defendants operate as a single integrated business. Upon information and belief, each Defendant acts as an agent of the other, and Defendants work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

13. Defendants know or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, New Jersey 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

15. Venue is proper against Defendants Aurobindo Pharma Limited and Auro Peptides Ltd., foreign corporations, in any judicial district that has personal jurisdiction, including this judicial district.

16. Venue is proper against Defendant Aurobindo Pharma USA Inc. because it operates a principal place of business in this judicial district and has committed an act of infringement in this judicial district.

THE PATENTS IN SUIT

17. The U.S. Patent and Trademark Office ("PTO") issued the '786 patent on May 9, 2006. The '786 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the '786 patent and have the right to sue for infringement thereof. A copy of the '786 patent is attached hereto as Exhibit A.

18. The PTO issued the '321 patent on April 4, 2017. The '321 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the '321 patent and have the right to sue for infringement thereof. A copy of the '321 patent is attached hereto as Exhibit B.

19. The PTO issued the '097 patent on April 11, 2017. The '097 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the '097 patent and have the right to sue for infringement thereof. A copy of the '097 patent is attached hereto as Exhibit C.

20. The PTO issued the '024 patent on March 20, 2018. The '024 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all

substantial rights in the ’024 patent and have the right to sue for infringement thereof. A copy of the ’024 patent is attached hereto as Exhibit D.

21. The PTO issued the ’231 patent on March 27, 2018. The ’231 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the ’231 patent and have the right to sue for infringement thereof. A copy of the ’231 patent is attached hereto as Exhibit E.

22. The PTO issued the ’637 patent on July 3, 2018. The ’637 patent claims, *inter alia*, purified peptides and processes of purifying peptides. Plaintiffs hold all substantial rights in the ’637 patent and have the right to sue for infringement thereof. A copy of the ’637 patent is attached hereto as Exhibit F.

23. The PTO issued the ’549 patent on October 12, 2021. The ’549 patent claims, *inter alia*, oral formulations of a purified peptide. Plaintiffs hold all substantial rights in the ’549 patent and have the right to sue for infringement thereof. A copy of the ’549 patent is attached hereto as Exhibit G.

24. The PTO issued the ’346 patent on May 3, 2022. The ’346 patent claims, *inter alia*, oral formulations of a purified peptide. Plaintiffs hold all substantial rights in the ’346 patent and have the right to sue for infringement thereof. A copy of the ’346 patent is attached hereto as Exhibit H.

25. Salix is the holder of NDA No. 208745 for Trulance®, which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the ’786, ’321, ’097, ’024, ’231, ’637, ’549, and ’346 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

26. Plecanatide oral tablets, 3 mg, are sold in the United States under the trademark Trulance®.

DEFENDANTS' INFRINGING ANDA SUBMISSION

27. Upon information and belief, Aurobindo Pharma Limited filed or caused to be filed with the FDA ANDA No. 217007, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

28. Upon information and belief, Defendants' ANDA No. 217007 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Defendants' generic plecanatide oral tablets, intended to be generic versions of Trulance®.

29. Plaintiffs received a letter dated November 28, 2022, purporting to be a Notice of ANDA No. 217007 with Paragraph IV Certifications ("Defendants' Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Defendants' Notice Letter was addressed to Salix and Bausch.

30. Upon information and belief, Defendants acted in concert to prepare and submit Defendants' ANDA No. 217007 and Defendants' Notice Letter.

31. Defendants' Notice Letter alleges that Aurobindo Pharma Limited submitted ANDA No. 217007 to the FDA seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' generic plecanatide oral tablets, intended to be generic versions of Trulance®.

32. Defendants' Notice Letter states that Defendants' ANDA No. 217007 "contains the required bioavailability and/or bioequivalence data" for Defendants' generic plecanatide oral tablets.

33. Defendants' Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, provides no explanation of any non-infringement defense related to the '786 patent, the '549 patent, and the '346 patent, and

provides no legitimate explanation of any non-infringement defense related to the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent, or the ’637 patent.

34. In Defendants’ Notice Letter, Defendants offered confidential access to portions of its ANDA No. 217007, on terms and conditions set forth in the Defendants’ Notice Letter (“the Defendants’ Offer”). Defendants required that Plaintiffs accept the Defendants’ Offer before receiving access to Defendants’ ANDA No. 217007. The Defendants’ Offer contains unreasonable restrictions well beyond those that would apply under a protective order.

35. Upon information and belief, ANDA No. 217007 seeks approval of Defendants’ generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

36. Upon information and belief, Defendant Aurobindo Pharma Limited’s actions related to ANDA No. 217007 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Aurobindo Pharma USA Inc. and Auro Peptides Ltd.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the ’786 Patent Under § 271(e)(2)

37. Paragraphs 1–36 are incorporated herein as set forth above.

38. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’786 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the expiration date of the ’786 patent.

39. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’786 patent.

40. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

41. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '786 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '786 Patent

42. Paragraphs 1–41 are incorporated herein as set forth above.

43. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

45. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '786 patent, including Defendants' filing of ANDA No. 217007.

46. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

47. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '786 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the ’321 Patent Under § 271(e)(2)

48. Paragraphs 1–47 are incorporated herein as set forth above.

49. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’321 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the expiration date of the ’321 patent.

50. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’321 patent.

51. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’321 patent.

52. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’321 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’321 Patent

53. Paragraphs 1–52 are incorporated herein as set forth above.

54. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

56. Defendants have made, and will continue to make, substantial preparation in the

United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '321 patent, including Defendants' filing of ANDA No. 217007.

57. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '321 patent.

58. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '321 patent.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '097 Patent Under § 271(e)(2)

59. Paragraphs 1–58 are incorporated herein as set forth above.

60. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '097 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '097 patent.

61. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '097 patent.

62. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '097 patent.

63. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '097 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’097 Patent

64. Paragraphs 1–63 are incorporated herein as set forth above.

65. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

67. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’097 patent, including Defendants’ filing of ANDA No. 217007.

68. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’097 patent.

69. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’097 patent.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the ’024 Patent Under § 271(e)(2)

70. Paragraphs 1–69 are incorporated herein as set forth above.

71. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’024 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the

expiration date of the ’024 patent.

72. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’024 patent.

73. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’024 patent.

74. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’024 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’024 Patent

75. Paragraphs 1–74 are incorporated herein as set forth above.

76. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

78. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’024 patent, including Defendants’ filing of ANDA No. 217007.

79. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’024 patent.

80. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '024 patent.

COUNT IX FOR PATENT INFRINGEMENT

Infringement of the '231 Patent Under § 271(e)(2)

81. Paragraphs 1–80 are incorporated herein as set forth above.

82. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '231 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '231 patent.

83. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '231 patent.

84. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.

85. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '231 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '231 Patent

86. Paragraphs 1–85 are incorporated herein as set forth above.

87. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

88. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

89. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '231 patent, including Defendants' filing of ANDA No. 217007.

90. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.

91. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '231 patent.

COUNT XI FOR PATENT INFRINGEMENT

Infringement of the '637 Patent Under § 271(e)(2)

92. Paragraphs 1–91 are incorporated herein as set forth above.

93. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '637 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '637 patent.

94. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '637 patent.

95. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the ’637 patent.

96. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’637 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’637 Patent

97. Paragraphs 1–96 are incorporated herein as set forth above.

98. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

100. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’637 patent, including Defendants’ filing of ANDA No. 217007.

101. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’637 patent.

102. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’637 patent.

COUNT XIII FOR PATENT INFRINGEMENT

Infringement of the ’549 Patent Under § 271(e)(2)

103. Paragraphs 1–102 are incorporated herein as set forth above.

104. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’637 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the expiration date of the ’549 patent.

105. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’549 patent.

106. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’549 patent.

107. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’549 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’549 Patent

108. Paragraphs 1–107 are incorporated herein as set forth above.

109. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

110. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

111. Defendants have made, and will continue to make, substantial preparation in the

United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '549 patent, including Defendants' filing of ANDA No. 217007.

112. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '549 patent.

113. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '549 patent.

COUNT XV FOR PATENT INFRINGEMENT

Infringement of the '346 Patent Under § 271(e)(2)

114. Paragraphs 1–113 are incorporated herein as set forth above.

115. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '346 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217007 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '346 patent.

116. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '346 patent.

117. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '346 patent.

118. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '346 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’346 Patent

119. Paragraphs 1–118 are incorporated herein as set forth above.

120. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

121. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

122. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’346 patent, including Defendants’ filing of ANDA No. 217007.

123. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’346 patent.

124. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’346 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’786 patent by submitting or causing to be submitted ANDA No. 217007 to

the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic plecanatide oral tablets before the expiration of the '786 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '321 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic plecanatide oral tablets before the expiration of the '321 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '097 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic plecanatide oral tablets before the expiration of the '097 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '024 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic plecanatide oral tablets before the expiration of the '024 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '231 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic plecanatide oral tablets before the expiration of the '231 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’637 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’637 patent;

7. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’549 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’549 patent;

8. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’346 patent by submitting or causing to be submitted ANDA No. 217007 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’346 patent;

9. Order that the effective date of any approval by the FDA of Defendants’ generic plecanatide oral tablets be a date that is not earlier than the expiration of the ’786 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent, the ’637 patent, the ’549 patent, and the ’346 patent, or such later date as the Court may determine;

10. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets until expiration of the ’786 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent, the ’637 patent, the ’549 patent, and the ’346 patent, or such later date as the Court may determine;

11. Enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendants' ANDA No. 217007 until expiration of the '786 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent, the '637 patent, the '549 patent, and the '346 patent;

12. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

13. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: January 12, 2023
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: January 12, 2023
Newark, New Jersey

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